EXHIBIT B

- **510(k) Summary for Pre-Formed Penile Silicone Block, dated May 9, 2022, and FDA Clearance Letter, dated May 13, 2022**

May 13, 2022

International Medical Devices, Inc.
% Allison C. Komiyama, Ph.D., R.A.C.
Principal Consultant
Rqm+
2251 San Diego Avenue, Suite B-257
San Diego, CA 92110

Re: K220760
Trade/Device Name: Pre-Formed Penile Silicone Block
Regulation Number: 21 CFR§ 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: II
Product Code: MIB
Dated: March 15, 2022
Received: March 15, 2022

Dear Allison C. Komiyama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220760

Device Name
Pre-Formed Penile Silicone Block

Indications for Use *(Describe)*
The Pre-Formed Penile Silicone Block is intended for use in augmentation, reconstructive and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. When used in augmentation procedures, the device provides cosmetic augmentation of the penis and is intended for aesthetic purposes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DATE PREPARED
May 9, 2022

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PROPRIETARY NAME OF SUBJECT DEVICE
Pre-Formed Penile Silicone Block

COMMON NAME
Elastomer, Silicone Block

DEVICE CLASSIFICATION
21 CFR 874.3620, Product Code MIB, Class II

CLASSIFICATION NAME
Ear, nose, and throat synthetic polymer material

PREDICATE DEVICE IDENTIFICATION
The Pre-Formed Penile Silicone Block is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K181387	Pre-Formed Penile Silicone Block / International Medical Devices, Inc.	✓

DEVICE DESCRIPTION
The Pre-Formed Penile Silicone Block is made from medical grade silicone with an embedded polyester mesh. The device comes in variations that include three sizes (L, XL, and XXL) and one durometer (“Soft”). Size “L” is 12 cm in length with a maximum thickness of 0.5 cm and a height

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of 2 cm. Size "XL" is 15 cm in length with a maximum thickness of 0.8 cm and a height of 3 cm. Size "XXL" is 18 cm in length with a maximum thickness of 1.1 cm and a height of 3.5 cm. The device is used in visual augmentation, reconstructive and cosmetic surgery for the penis, and may be trimmed to allow the surgeon to tailor the device to the needs of a specific patient.

Part #	*Part Description*	*Materials*
IMD006-L-S	IMD Block, Packaged Soft, Large, Sterile	Silicone and Polyester Mesh
IMD006-L-NS	IMD Block, Packaged Soft, Large, Non-sterile	
IMD006-XL-S	IMD Block, Packaged Soft, XL, Sterile	
IMD006-XL-NS	IMD Block, Packaged Soft, XL, Non-sterile	
IMD006-XXL-S	IMD Block, Packaged Soft, XXL, Sterile	
IMD006-XXL-NS	IMD Block, Packaged Soft, XXL, Non-sterile	

INDICATIONS FOR USE

The Pre-Formed Penile Silicone Block is intended for use in augmentation, reconstructive and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. When used in augmentation procedures, the device provides cosmetic augmentation of the penis and is intended for aesthetic purposes.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has identical dimensions, design, materials, and technological characteristics as the predicate device (K181387). The subject and predicate devices have the same intended use, as both are intended to be implanted in the penis as a space-occupying substance in cosmetic surgeries.

SUMMARY OF NON-CLINICAL TESTING

Because no changes in technological characteristics are made for the subject device compared to the predicate device, non-clinical testing, such as biocompatibility, sterilization validation, and non-clinical performance testing is not needed to support a substantial equivalence of the subject device to the predicate.

SUMMARY OF CLINICAL TESTING

The Pre-Formed Penile Silicone Block is intended for use in visual augmentation, reconstructive and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. In a retrospective study, 526 patients underwent elective cosmetic penile surgery using the Pre-Formed Penile Silicone Block over a period of five years. Approval from the Institutional Review Board was obtained to perform a retrospective analysis of the cosmetic surgery outcomes. Of the 526 patients who underwent elective cosmetic penile surgery using the subject device, 400 patients responded to the study author's request for consent and were included in the study. The outcomes of their surgeries are summarized here. Clinical effectiveness of the subject device was evaluated via changes in penile measurements, changes in the Augmentation Phalloplasty Patient Selection and Satisfaction Inventory (APPSSI), changes in patient self-confidence and self-esteem, and a change in the incidences of adverse events.

Penile circumference was measured before, immediately after, and 30-90 days after the implant surgery. In the 400 patients, the implantation of the Pre-Formed Penile Silicone Block increased midshaft circumference from an average of 8.5 ± 1.2 cm to 13.4 ± 1.9 cm, a 56.7% increase (P<.001). Six to eight weeks postoperatively, 83% of the surveyed patients noted a 2-category improvement in their self-confidence and self-esteem, and upon long-term follow-up (2-6 years, mean 4 years), 72% patients maintained a 2-category improvement in their APPSSI score, and 81% of subjects reported “high” or “very high” levels of satisfaction with their surgical outcome.

The most frequently reported postoperative complications were seroma (4.8%), scar formation (4.5%), and infection (3.3%). 3% of patients experienced adverse events that necessitated device removal. There were no reports of any changes to sexual function, erections, or ejaculations.

CONCLUSION

The subject device is identical in dimensions, design, materials, and technological characteristics and has the same intended use as the predicate device (K181387). It was determined that the subject device is as safe and effective as the predicate device because they have the same intended use and identical technological characteristics. Therefore, the subject device is substantially equivalent to the predicate device.